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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,638	10/10/2001	Chad A. Mirkin	00-713-i9	7336

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EXAMINER	
RILEY, JEZIA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/973,638	MIRKIN ET AL.	
	Examiner	Art Unit	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *125-129 and 156-161* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *129,157 and 161* is/are allowed.

6)☒ Claim(s) *125-128,156 and 158* is/are rejected.

7)☒ Claim(s) *159 and 160* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Priority

1. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a0 on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage

commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 128 recites the limitation "portion of the sequence of **the** nucleic acid" in lines 8 and 11. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 125-128, 156, and 158 are rejected under 35 U.S.C. 102(e) as being anticipated by Yguerabide et al. (6,214,560).

Yguerabide et al. discloses a method of light illumination and detection named "DLASLPD" (direct light angled for scattered light only from particle detected) disclose an analyte assay using gold particulate label for specific detection of one or more analytes in a sample. One or more analytes in a sample can be detected and measured by detection and/or measurement of one or more of the specific light scattering properties of metal-like particles. (Summary of the Invention). For example, a certain nucleic acid analyte is composed of about 100 nucleic acid bases and is present

in a sample. The sample is prepared so that this nucleic acid is in a single stranded form. Then two or more unique single-stranded "probe" nucleic acid sequences are added to the sample where these different probes bind to different regions of the target strand which is viewed to be inclusive of the sequences complementary to the sequence of the first or second portion of the nucleic acid of the instant claims. Each of these probes has attached to one or more particles which is viewed to be inclusive of the instant aggregate probes (col. 74). Further, the particles can form different types of aggregates that can be detected visually or instrumentally in a microscope or through macroscopic observation or measurements without having to separate free from analyte bound particles. The type of aggregates formed depends on the size of the cross-linking agent or agents and their valency and on the type of binding agent attached to the particle. Aggregates can range from two particles to many. The method can be used in a multi-analyte detection in the microarray format. The method provides for useful apparatus and particle types for specific test kits can be constructed. It is well known in the art that there is a wide range of analyte types. These analytes exist in different sample environments such as water, urine, blood, sputum, tissue, soil, air, and the like. Depending on the requirements of a particular type of analytic assay, one may want to get semi-quantitative or quantitative information, or both with regard to the analytes of interest. There are conditions where it is desirable to perform the analysis with a small, inexpensive, and highly portable instrument. For example, consumer use, use in the field (away from a lab), or at bedside in the hospital. One wants to be able to quickly get either semi-quantitative and/or quantitative measurements on the analytes in

question. In other applications, it is desirable to have a small and inexpensive instrument for analyte detection in a small lab where from a few to several samples are tested a day, capable of quantitative results. For example, doctor's office, clinic, satellite testing lab, research labs and the like. There are also conditions where one wants to test several hundred to thousand samples per day, such as high throughput testing. Each of the above testing conditions and environments thus require different types of apparatus means. The advantages and disadvantages in terms of ease of use and cost of such apparatus can only be determined in detail when the exact requirements of testing for the analyte(s) in a sample is well defined. They have determined that the use of certain metal-like particles with certain variations of the DLASLPD methods of detection allow for the development of specific test kits and apparatus for the above mentioned testing environments and applications. There are numerous different combinations of analytes, testing environments, sample types, assay formats, analyte detection requirements, and apparatus cost and size requirements. One of average skill in the art will recognize the tremendous utility of the invention in that the practice of the invention in one form or another leads to easy to use and inexpensive apparatus and test kits to solve most analytical or diagnostic testing needs. (col. 69, lines 30-67).

For sensitive detection of analytes in a small solid-phase area such as commonly used in microarray and array chip formats, certain types of metal-like particles are more preferred to use than others. Metal-like particles in microarray and array chip formats can be most easily and inexpensively detected by using DLASLPD methods. The reference provides for detection of one or more analytes in many different types of

samples and diagnostic assay formats. FIG. 11 presents a schematic diagram of a prism setup. In one of its simplest forms, it consists of a triangular prism on which can sit microtiter wells, glass slides, microarrays on plastic or glass substrates and the like which contain the light scattering particles to be detected. (col. 64, lines 13-17). A light scattering particle(s) is attached directly or indirectly to areas of the molecular substrate such that the cleavage process is minimally affected. (col. 74, lines 41-67).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 125, 126, 156 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31 and 33 of U.S. Patent No. 6,506,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claims kit comprising containers holding oligonucleotides (the oligonucleotides of the patent being viewed to be inclusive

of the aggregate probe of the instant application) comprising at least two types of nanoparticles having sequences complementary to different portions of a nucleic acid.

6. Claims 159, 160 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 129, 157, and 161 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JEZIA RILEY
PRIMARY EXAMINER